

REMARKS

Claims 57 and 58 were previously pending in this application. Claim 57 has been canceled without prejudice to or disclaimer of the underlying subject matter, and new claims 59-72 have been added. Support for the new and amended claims can be found throughout the specification, for example, at page 37, line 6 through page 40, line 22, in the sequence listing, and in the claims as originally filed and in the Tables. The specification has been amended at the request of the Examiner to add SEQ ID NOs next to the sequences on page 52, lines 6 and 7. No new matter enters by way of these amendments.

1. Continued Examination under 37 CFR § 1.114

Applicants acknowledge the Examiner's withdrawal of finality of the previous Office Action pursuant to 37 CFR 1.114.

Furthermore, Applicants acknowledge and thank the Examiner for entry of the amendment of October 28, 2002 amending the title of the invention.

2. Specification – Sequence Identification

The specification has been objected to for containing “two sequences without SEQ ID NOs.” Office Action at pages 2-3. Applicants have amended the specification such that the sequences listed on page 52, lines 6 and 7 cite to the corresponding SEQ ID NOs in the amended CRF of the sequence listing.

In light of these amendments, applicants respectfully request withdrawal of this objection to the specification.

3. Sequence Listing

The sequence listing has been amended in response to the Examiner’s request that the sequence listing include the sequences listed on page 52, lines 6 and 7. An amended CRF of the sequence listing is attached hereto.

4. Claim Rejections – 35 U.S.C. § 101

Claims 57 and 58 have been rejected under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility “due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.” Office Action at page 4. Claim 57 has been canceled without prejudice to or disclaimer of the underlying subject matter, so Applicants will respond to the rejection only as it pertains to claim 58.

It is well established that “when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown.” *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 298 (Fed. Cir. 1983). The present

specification describes many objectives that are met by the claimed methods of the present invention. As described in the instant specification, the claimed methods find numerous uses, for example for transcription profiling, identifying counterpart genes in other species and identifying open reading frames (ORFs). *See, e.g.*, specification page 2, lines 10 through 13 and page 38, lines 11 through 14. Another disclosed use of the claimed methods is in the detection of the presence, absence or level of an organism, for example *E. nidulans*, in a given sample. *See, e.g.* page 37, lines 7 through 9 and page 30, lines 19 through 21. Any one of the above uses is enough to satisfy the § 101 requirement.

The Examiner ignores the disclosed utilities of the claimed methods and simply argues that the nucleic acid molecules used in the methods lack patentable utility. More specifically, the Examiner alleges that the patentability of the “claims is based on a computer readable medium with at least 100 nucleic acid sequences recorded thereon.” Office Action at page 4. Applicants respectfully disagree with the Examiner.

Claims must be considered as a whole in determining compliance with § 101. *Diamond v. Diehr*, 450 U.S. 175, 188, 209 U.S.P.Q. 1, 9 (1981). It is inappropriate to dissect claims and consider some elements while ignoring others. *Id.* Applicants respectfully submit that they are not claiming the “computer readable medium with at least 100 nucleic acid sequences recorded thereon” in the abstract. Applicants have disclosed sequences of *E. nidulans* that comprise virtually the entire genome of this organism. The amended claims however are directed as a whole to methods of identifying nucleotide sequences where the methods comprise, *inter alia*, the use of a “computer readable medium with at least 100 nucleic acid sequences recorded thereon.”

Accordingly, the Examiner's assertion that the patentability of the claims is based on the computer readable medium alone is improper.

Applicants respectfully submit that the claimed methods are supported by a specific, substantial and credible utility. In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the methods or the nucleic acid sequences used in the methods. Rather the Examiner attempts to undermine the existing utilities by stating that "the disclosed uses are generally applicable to any sequence data recorded on computer readable medium." Office Action at pages 4. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other sequences stored on computer readable medium can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result...").

Such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 306 U.S.P.Q. 193, 196 (1980), quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 163 (1933). Thus, it must be the case that a utility, generic to a broad class of nucleic acid sequences recorded on computer readable medium, does not compromise the specific utility of an individual member of that class.

The nucleic acid sequences recorded on computer readable medium used in the methods of the present invention have many utilities. Some of these utilities may be common to a broader class of sequences recorded on computer readable medium. For instance, nucleic acid sequences recorded on computer readable medium may generally be used to identify related sequences. However, when used in this manner, the result is not generic. Rather, the nucleic acid sequences recorded on computer readable medium used in the claimed methods will identify a *unique* subset of related sequences. This subset of related sequences is specific to the recorded sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid sequence would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit a ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed methods exhibit the requisite utility under 35 U.S.C. § 101.

The Examiner also argues that utility is lacking because “there is no indication in the specification of what are the functions of any” of the sequences recited in the claimed methods. Office Action at pages 4. Applicants respectfully submit that the specification provides ample disclosure of the functions of these sequences. Such disclosure can be found for example in Table 2. For example, Table 2 discloses that SEQ ID NO: 16218 is a chitinase protein. The Examiner has not provided sufficient support (legal or factual) to rebut the asserted functions. Thus, Applicant’s respectfully submit that the specification does indicate functions for the sequences used in the methods of the present invention.

The Examiner has not assessed the credibility of the presently asserted utilities. Credibility is precisely the issue that the courts have emphasized in evaluating the

adequacy of an asserted utility. Utility is determined “by reference to, and a factual analysis of, the disclosure of the application.” *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), quoting *Cross v. Iizuka*, 752 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner “has the initial burden of challenging a presumptively correct assertion of utility in the disclosure.” *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner “must do more than merely question – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability.” *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); M.P.E.P. § 706.03(a)(1) (“Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...”). Here the Examiner has not even attempted to meet this burden.

In view of the above, Applicants contend that the claimed methods are supported by credible, specific and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claim 58 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

5. Claim Rejections – 35 U.S.C. § 112, first paragraph, enablement

Claims 57 and 58 were rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification, because the claimed invention allegedly lacks utility (*i.e.*, an invention with no utility cannot be enabled). Claim 57 has been cancelled without prejudice to or disclaimer of the underlying subject matter, so Applicants will respond to the rejection only as it pertains to claim 58. Applicants respectfully traverse this rejection as it pertains to claim 58, and note that this rejection has been overcome by the foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph, is improper. Reconsideration and withdrawal are respectfully requested.

6. Claim Rejections – 35 U.S.C. § 112, first paragraph, written description

Claims 57 and 58 were rejected under 35 U.S.C. § 112, first paragraph, as containing “subject matter which was not described in the specification in such a way as to reasonably convey” to the skilled artisan “that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner argues that there is no support in the original specification for the specific selection of the 100 sequences in the pending claims. Applicants respectfully submit that original claim 29 reads “[a] computer readable medium having recorded thereon at least 100 of the nucleotide sequences depicted in SEQ ID NO: 16207 through SEQ ID NO: 27905 or complements thereof.” In light of the specific disclosure of 100 sequences, Applicant’s respectfully do not understand the Examiner’s rejection of the claims under

35 U.S.C. §112, first paragraph. Applicants respectfully request the Examiner clarify the written description rejection in light of the above.

7. Claim Rejections – M.P.E.P. § 2106

Claims 57 and 58 are rejected based on the argument that “sequences stored on a computer readable medium are ... considered as non-functional descriptive material” and therefore do not qualify as patentable subject matter. Claim 57 has been canceled without prejudice to or disclaimer of the underlying subject matter, accordingly Applicants will respond to the rejection only as it pertains to claim 58.

Applicants respectfully point out that claim 58 is directed to a method of identifying a nucleotide sequence comprising comparing a target sequence to a sequence stored in computer readable medium having recorded thereon at least 100 nucleotide sequences including sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof. Claim 58 accordingly defines a process, as it requires one or more acts to be performed. MPEP 2106.B.2.(b) at page 2100-15.

“A series of steps is a ‘process’ within § 101 unless it falls within a judicially determined category of nonstatutory subject matter exceptions.” *In re Sarkar*, 588 F.2d 1330, 1333, 200 USPQ 132, 137 (CCPA 1978). The courts have recognized several narrow exceptions for “laws of nature, natural phenomena, and abstract ideas.” *See, e.g.*, *In re Alappat*, 33 F.3d 1526, 1542, 31 USPQ2d 1545, 1556 (Fed. Cir. 1994) (in banc) (citing *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)). The heart of the statutory subject matter inquiry is whether the claimed subject matter as a whole is directed to a “practical

application,” which the courts have defined as “a useful, concrete and tangible result.

State Street Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368, 1375, 47 USPQ2d 1596, 1602 (Fed. Cir. 1998).

The MPEP provides that for a process claim involving a computer-related step to be statutory, the process must either: “(A) result in a physical transformation outside the computer for which practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan, or (B) be limited to a practical application within the technological arts.” MPEP 2106 B.2.(b) at page 2100-15. “A method is limited to a practical application when the method, as claimed, produces a concrete, tangible and useful result. *Id.* at page 2100-18 (citing *AT&T Corp.*, 172 F.3d at 1358, 50 U.S.P.Q.2d at 1452).

Applicants respectfully submit that the method of claim 58 is directed to a “practical application.” As stated above claim 58 recites the steps of comparing a target sequence to a sequence stored in computer readable medium having recorded thereon at least 100 nucleotide sequence including sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof. This method is directed to the “useful, concrete and tangible result” of identifying nucleotide sequences within the biotechnological arts.

The Examiner cites to language in the MPEP to support the proposition that “purely non-functional descriptive material cannot alone provide the practical application for the manufacture.” Office Action at page 6. Assuming *arguendo* that the sequences stored on a computer readable medium are non-functional descriptive material and are therefore not patentable subject matter alone, this fact would not render the instantly

claimed methods unpatentable. Such a situation is analogous to the use of mathematical algorithms in claimed methods. A mathematical algorithm in the abstract is not patentable subject matter, yet the Federal Circuit has found methods reciting steps involving mathematical algorithms to fit within the statutory subject matter. *See, e.g.*, *AT&T Corp. v. Excel Commun., Inc.*, 172 F.3d 1352, 50 U.S.P.Q.2d 1447 (Fed. Cir. 1999). The method of claim 58 recites a step involving comparing a target sequence to a sequence stored in computer readable medium having recorded thereon at least 100 nucleotide sequences including the sequences of SEQ ID NO: 16207 through SEQ ID NO: 27905. As argued above, this step is used in a method that provides the “useful, concrete and tangible result” -- identifying a nucleotide sequence.

In view of the above, Applicants contend that the claimed methods fall within the statutory subject matter of a process. Consequently, the rejection of claim 58 as non-functional descriptive material under MPEP 2106.VI is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

8. Claim Rejections – 35 U.S.C. § 103 Rejections

Claims 57 and 58 have been rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Rodrigues-Tome, *et al.* (Nucl. Acids Res., vol 24, pp. 6-12, 1996) (“Rodriguez-Tome, *et al.*”). Claim 57 has been canceled without prejudice to or disclaimer of the underlying subject matter, so Applicants will respond to the rejection only as it pertains to claim 58.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. There

must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The teaching or suggestion to make the claimed combination must be found in the prior art, and not be based on applicant's disclosure.

See M.P.E.P. §§2143.01 and 2143.03.

In a proper obviousness determination, the changes from the prior art must be evaluated in terms of the whole invention, including whether the prior art provides any teaching or suggestion to one of ordinary skill in the art to make the changes that would produce the claimed invention. *See In re Chu*, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995). This includes what could be characterized as simple changes. *See, e.g., In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984) (Although a prior art device could have been turned upside down, that did not make the modification obvious unless the prior art fairly suggested the desirability of turning the device upside down.).

Only when the prior art teaches or suggests the claimed invention does the burden fall on the applicant to rebut that *prima facie* case. *See In re Dillon*, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (in banc), *cert. denied*, 500 U.S. 904 (1991). However, a *prima facie* case of obviousness may be rebutted by showing that the art, in any material respect, teaches away from the claimed invention.

The present invention is drawn to a method of identifying a nucleotide sequence comprising comparing a target sequence to a sequence stored in computer readable medium having recorded thereon at least 100 nucleotide sequences including sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof.

The Examiner argues that Rodrigues-Tome *et al.* discloses “comparing users’ sequences (=target sequences) to sequence in the EMBL nucleotide sequence database (page 10, paragraph 8).” Rodrigues-Tome *et al.*, however, does not teach the sequences “selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof.” The Applicants respectfully submit that the cited reference does not render the present independent claims obvious, since the claims are not taught nor suggested by the cited references. The cited references do not disclose or suggest the sequences of *E. nidulans* taught in the present disclosure.

The Examiner has stated that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used the methods taught by Rodriguez-Tome *et al.* to perform sequence searches against a collection of sequence data. Office Action at page 7. The Examiner asserts that the “motivation to do so would have been that using CD-ROM made database searches accessible to clients without Internet access.” *Id.* The Examiner has not, however, asserted where any of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof are disclosed by Rodrigues-Tome *et al.*

In sum, the Examiner’s conclusion of obviousness is based on improper hindsight reasoning. “Impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.” M.P.E.P. § 2142 at 2100-124. No suggestion to modify the cited references has been found in the cited references or pointed out to Applicant from the general knowledge of one of ordinary skill in the art. In addition, no indication for Rodrigues-Tome *et al.* teaching the sequences used in the claims is provided. For at least these reasons, the Applicant respectfully submits that the

Examiner has failed to establish a *prima facie* case of obviousness, as required by 35 U.S.C. § 103.

Accordingly, for at least the foregoing reasons, the rejection of claims 57 and 58 under 35 U.S.C. § 103 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,



David R. Marsh (Reg. Atty No. 41,408)
Holly Logue Prutz (Reg. Atty No. 47,755)
Thomas E. Holsten (Reg. Agent No. 46,098)

ARNOLD & PORTER
555 Twelfth Street, NW
Washington, D.C. 20004
(202) 942-5000 telephone
(202) 942-5999 facsimile

Date: December 29, 2003

Correspondence Address:
MONSANTO COMPANY
800 N. Lindbergh Blvd.
Mailzone N2NB
St. Louis, MO 63167
(314) 694-3602 telephone
(314) 694-1671 facsimile